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| APPLICATION NO. | 1 61 | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| APPLICATION NO. | | LING DATE | TRST NAMED INVENTOR | ATTORNET BOCKET NO. | CONTINUATION NO. |
| 10/612,170 | (| 07/01/2003 | Vahid C. Saadat | USGI-004 A | 5203 |
| 20350 | 7590 | 03/29/2006 | | EXAM | INER |
| TOWNSE | ND AND | TOWNSEND AN | ND CREW, LLP | MENDOZA, MICHAEL G | |
| TWO EMBA | ARCADE | RO CENTER | | | |
| EIGHTH FI | | | | ART UNIT | PAPER NUMBER |
| SAN FRAN | CISCO. C | A 94111-3834 | | 3734 | |

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| At . | Application No. | Applicant(s) |
| | 10/612,170 | SAADAT ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Michael G. Mendoza | 3731 |
| The MAILING DATE of this communicate Period for Reply | ation appears on the cover sheet with | n the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAIN - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this commun. If NO period for reply is specified above, the maximum statul. Failure to reply within the set or extended period for reply will Any reply received by the Office later than three months afte earned patent term adjustment. See 37 CFR 1.704(b). | ILING DATE OF THIS COMMUNIC 37 CFR 1.136(a). In no event, however, may a relication. It is period will apply and will expire SIX (6) MONT III. by statute, cause the application to become ABA | ATION. bly be timely filed HS from the mailing date of this communication. INDONED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed | on <u>13 January 2006</u> . | |
| 2a)⊠ This action is FINAL . 2b | o) This action is non-final. | |
| 3) Since this application is in condition fo closed in accordance with the practice | | |
| Disposition of Claims | | |
| 4) Claim(s) 1-49 is/are pending in the appear 4a) Of the above claim(s) 15,17,19,22-5) Claim(s) is/are allowed. 6) Claim(s) 1-9,11-14,16,18,20,21,26,27 7) Claim(s) 10 is/are objected to. 8) Claim(s) are subject to restriction | - <u>25,28 and 30-49</u> is/are withdrawn f <u>and 29</u> is/are rejected. | rom consideration. |
| Application Papers | | |
| 9) The specification is objected to by the | Examiner. | |
| 10) The drawing(s) filed on is/are: a | a) accepted or b) objected to b | y the Examiner. |
| Applicant may not request that any objecti | ion to the drawing(s) be held in abeyand | e. See 37 CFR 1.85(a). |
| Replacement drawing sheet(s) including the same of the | | |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for a) All b) Some * c) None of: 1. Certified copies of the priority do 2. Certified copies of the priority do | ocuments have been received. ocuments have been received in Ap f the priority documents have been al Bureau (PCT Rule 17.2(a)). | oplication No received in this National Stage |
| Attachment(s) | 4) Tateniew S | ummary (PTO-413) |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-3) Information Disclosure Statement(s) (PTO-1449 or P Paper No(s)/Mail Date | O-948) Paper No(s |)/Mail Date formal Patent Application (PTO-152) |

Art Unit: 3731

DETAILED ACTION

Response to Arguments

- 1. Applicant's arguments filed 13 January 2006 have been fully considered but they are not persuasive. The applicant argues that Ewers et al. cannot be ejected from a delivery device. The examiner disagrees. The applicant has not positively claim a delivery device. The limitation of "adapted to be ejected from a delivery device" is a functional limitation and does not result in a structural difference. The device of Ewers et al. need only be capable of being ejected from a delivery device. Ewers et al. is fully capable of being ejected from a delivery device
- 2. The applicant argues that the device of Ewers et al. is not configured so that application of tension on the suture approximates the distal bushing to the proximal bushing. The device of Ewers et al. needs only to be capable of performing the claimed limitation. The device of Ewers et al. is fully capable of performing the recited limitation. An example of how the device of Ewers et al. can perform the recited function is by starting with the configuration as shown in FIG. 5. By grasping and holding proximal bushing 27 in place at a distal position as shown in FIG. 5 then pulling the suture 34 in the proximal direction would cause distal bushing 30 to move proximally towards the distal bushing. The device of Ewers et al. reads on the claim limitation.
- 3. The applicant argues that the device of Ewers et al. does not teach struts. The examiner disagrees. As shown in FIG. 6, Ewers shows struts 40 as described in col. 9, line 2-5.

Art Unit: 3731

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claims 1-9, 11, 16, 18, 20, 21, 26, 27, and 29 are rejected under 35
 U.S.C. 102(e) as being anticipated by Ewers et al. 6589208.
- 1-9, and 11, Ewers et al. teaches an anchor comprising: a sleeve 32 including proximal 27 and distal bushings 30; wherein the sleeve is adapted to be reconfigured from a reduced delivery profile to an expanded deployed profile (fig. 3 & 4); a suture 34 coupled to the distal bushing and extending through the interior of the sleeve; wherein the suture extends through an aperture in the proximal bushing (see figs.); wherein the sleeve is configured so that application of tension on the suture approximates the distal bushing to the proximal bushing (col. 7, lines 55-67); wherein the sleeve is configured so that application of tension on the suture transitions the sleeve from the reduced delivery profile to the expanded deployed profile (col. 7, lines 55-67); wherein the sleeve is braided (see figs.); wherein the sleeve is formed of individual monofilament elements; wherein the monofilament elements are made of polyester, nylon, TEFLON, polypropylene or combinations of these materials (col. 6, lines 39-41); wherein the

Art Unit: 3731

sleeve comprises a shape memory material; an internal lock for retaining the sleeve in the expanded deployed profile (col. 3, lines 32-51).

As to claims 16, 18, 20, 21, 26, 27, and 29, Ewers et al. teaches an anchor 7. comprising: a shank having proximal and distal ends; and a reconfigurable member disposed on the distal end of the shank, the reconfigurable member having a reduced delivery profile and an expanded deployed profile; wherein the reconfigurable member comprises a plurality of struts affixed to the distal end of the shank/fixation point, a suture coupled to the fixation point; the plurality of struts having a reduced delivery profile wherein the plurality of struts are substantially parallel to the shank and an expanded deployed profile wherein the plurality of struts extend at angles away from the shank; wherein the shank is arranged so that tension applied to the shank urges the reconfigurable member to the expanded deployed profile; wherein the reconfigurable member comprises a shape memory material; wherein the fixation point comprises a distal bushing and distal end of each on of the plurality of struts is coupled to the distal bushing and the proximal end of each on of the plurality of struts is coupled to a proximal bushing; and wherein in the expanded deployed profile, the plurality of struts bow radially outward to form a disk-like configuration (fig. 6).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 3731

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers et al. in view of Gannoe et al. 6746460.

10. Ewers et al. teaches the anchor of claim 1. It should be noted that Ewers et al. fails to teach a coating of bioactive agent applied to an outer surface of the sleeve. However, Gannoe et al. teaches a device used for gastric reduction having a bioactive agent coating. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a bioactive coating to the device of Evers et al. to promote healing or protect against infection (col. 5, lines 9-11).

Allowable Subject Matter

11. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 10/612,170

Art Unit: 3731

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

WV

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GARY JACKSON PRIMARY EXAMINER GROUP 3300